Message

From: McGrath, Jesse [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C34718C70BB64FE58E72FA1AB387E90E-JMCGRA02]
Sent: 6/1/2017 9:26:50 PM
To: CAMALIER, LOUISE [LOUISE.CAMALIER@oig.usda.gov]
Subject: Overview of the QA CFR and guidance and my request
Attachments: data validation v0.3 short.pptx; controlCharts1987-2016.pdf

Thanks Louise,

I really enjoyed the conversation and thanks for looking at this for me,

Coincidentally I just sent this to another Louise. I'm trying to make a procedural argument with this other group – we can't require states to invalidate using this method because it's not in the CFR. But also need support on the scientific and historical part.
"The scientific part" below is my attempt at an explanation for normal people and the citations are below that. There are more extensive citations in the attached document.

The QA handbook templates start at page 202 of the linked pdf, and the ozone template they are citing is on page 206.

To recap what I'm looking for:

1) The effect invalidating QC points when they are extremities of a valid error distribution has on the summary statistics.
    a. My understanding is that this will bias the results to appear better than they are.
    b. If there is a physical failure the data are invalid of course.
2) The intent of the QC checks and the 7% action limits.
    a. My understanding is the QC checks are to measure the error distribution, regardless of how "good" or "bad" it is.
    b. They can also be used as a warning system by identifying outlying points.
3) The historical use of the checks.
    a. I believe they have been used as I expect, and not to invalidate data.
    b. I attached some charts of the all the ozone checks for every monitor in nation. I see no indication the checks have been used this way historically.

Overview

The method OAQPS is using to invalidate data misrepresents the data quality as better than it really is, and actually undermines our ability to use the data. The CFR and guidance are clear that we should not use this approach. In the last few years people in the region and RTP have been pushing for this specific in-and-out approach that they claim is commonly used ,and supported by the guidance. I find the guidance says not to do it, and that the states historically have not used this approach, and know not to.

The scientific part

To use a sports analogy, a batter can't say a strike "doesn't count" against his batting average just because he swung a strike, there must be something unusual to discount it, such as an illegal pitch, or a fan on the field. Strikes accurately reflect his performance, even if it's poor. So, when reviewing data quality you must distinguish between data-wide issues, which require that you use or not use all the data, and issues that affect a portion of the data, where that portion may be invalidated and removed from the data set. When you don't, you might mislead others and yourself about how good the data are; a batter excluding strikes to puff up his batting average for recruiters would find himself in a lot of trouble.
We use a known concentration of pollutant to check instrument quality, and if you simply invalidate every value where the check exceeds some number you will always appear to meet your goal, puffing up your quality assurance numbers in the same way as the batter.

The CFR and guidance

The CFR section is here: https://www.ecfr.gov/cgi-bin/text-idx?SID=20634c28300ba7afb67db98abcd2961d&node=ap40.6.58_161.a&rgn=div9

The most relevant section is below with my emphasis.

It is clear we must use a weight of evidence approach. It mentions using validation templates also, which people are using to somehow avoid an actual weight of evidence approach.

> 1.2.3 Each PQAO is required to implement a quality system that provides sufficient information to assess the quality of the monitoring data. The quality system must, at a minimum, include the specific requirements described in this appendix. *Failure to conduct or pass a required check or procedure, or a series of required checks or procedures, does not by itself invalidate data for regulatory decision making. Rather, PQAOs and the EPA shall use the checks and procedures required in this appendix in combination with other data quality information, reports, and similar documentation that demonstrate overall compliance with Part 58.* Accordingly, the EPA and PQAOs shall use a "weight of evidence" approach when determining the suitability of data for regulatory decisions. The EPA reserves the authority to use or not use monitoring data submitted by a monitoring organization when making regulatory decisions based on the EPA's assessment of the quality of the data. Consensus built validation templates or validation criteria already approved in QAPPs should be used as the basis for the weight of evidence approach.

The measurement goals for ozone are in this citation.

They are aggregated statistics of individual checks, and not limits on individual checks. In other words, a group of checks with a standard deviation of 7% will have many individual checks outside of 7%. That's very important later when looking at the validation templates.

> 2.3.1.2 *Measurement Uncertainty for Automated O_3 Methods.* The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the CV of 7 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 7 percent.

OAQPS is citing the QA handbook validation templates, available here:

https://www3.epa.gov/ttnamti1/files/ambient/pm25/qa/QA-Handbook-Vol-II.pdf

See Appendix D page 2 for their major citation and page 5 for the criterion they are looking at.

There's a lot more to the handbook than that, and notice that the entire section and that specific criterion are recommendations.

I can't cite all of the necessary parts here, but their interpretation of the paragraph below is internally inconsistent with the rest of the QA handbook, and inconsistent with the other guidance and CFR.

However, interpreting it as a requirement to investigate and act makes it fully consistent. I've also talked with one of the authors of the Handbook and they said it was not meant to be interpreted as OAQPS is doing.

> Criteria that were deemed critical to maintaining the integrity of a sample or group of samples were placed on the first table. Observations that do not meet each and every criterion on the Critical Criteria Table should be invalidated unless there are compelling reason and justification for not doing so. The sample or group of samples for which one or more of these criteria are not met is invalid until proven otherwise. The cause of not operating in the acceptable range for each of the violated criteria **must be investigated** and minimized to reduce the likelihood that additional samples will be invalidated.

Other citations:

I attached a presentation I've used to talk about this before. I copied out the most relevant citations..

Guideline on the Meaning and Use of Precision and Accuracy Data Required by 40 CFR Part 58, Appendices A and B is here: https://www3.epa.gov/ttnamti1/files/ambient/qaqc/023.pdf

And says "The intended use of the precision and accuracy checks is not for the use as data validation and invalidation checks" [Their emphasis]. Which is standard across the board for how to use precision and accuracy checks, they are at best warning indicators.

And the prior version of the QA handbook says. I can provide a copy of this if needed.

"Data quality assessment measurements (precision and accuracy checks) are not intended to be used for data validation/invalidation. ... review all pertinent quality control information to determine whether any ambient data, as well as any associated assessment data, should be invalidated.
However, this means should not be used merely to improve the data quality of specific analyzers or of the reporting agency." [my emphasis]

That last sentence is crucial because OAQPS' implementation of this does exactly that. Both documents are clear that the precision and accuracy data should not be used in the way they are using them.

Summary
OAQPS is mandating a specific interpretation of a half-sentence from the guidance that is in itself a well-known form of biasing data, and contradicts 40 years of guidance and actual implementation at EPA, and centuries of basic data collection principles. Doing this will put the public at risk because of the effect on NAAQS designations, and put the Agency's reputation as a trustworthy source of data in jeopardy.

-----Original Message-----
From: CAMALIER, LOUISE [mailto:LOUISE.CAMALIER@oig.usda.gov]
Sent: Thursday, June 01, 2017 3:28 PM
To: McGrath, Jesse <mcgrath.jesse@epa.gov>
Subject: RE: Test email

Got it!

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-----Original Message-----
From: McGrath, Jesse [mailto:mcgrath.jesse@epa.gov]
Sent: Thursday, June 01, 2017 3:27 PM
To: CAMALIER, LOUISE <LOUISE.CAMALIER@oig.usda.gov>
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